

## **REMARKS**

The pending Office Action addresses claims 10-14, 16-21, 24-41, 43, 44, 47-54, 56-64, and 67-73, all of which stand rejected. Reconsideration and allowance are requested in light of the amendments and remarks submitted herewith.

### ***Amendments to the Figures***

The Office Action objects to Figures 7a, 7b, 7c, and 8-13. The Examiner maintains that elements within the figures are not labeled with indicia indicative of their function.

Applicants respectfully submit that all drawings are in conformity with the requirements for drawings as described in 37 C.F.R. 1.84. Applicants note that 37 C.F.R. 1.84 does not require that elements within a figure be labeled with indicia indicative of their function. Rather, it provides in relevant part that “[r]eference characters not mentioned in the description shall not appear in the drawings. Reference characters mentioned in the description must appear in the drawings.” 37 C.F.R. 1.84(p)(5). The reference characters of the figures to which the Examiner objects are mentioned within the specification. Accordingly, Applicants believe these figures comply with 37 C.F.R. 1.84.

Nonetheless, Applicants submit amended Figures 7a, 7b, 7c, and 8-13 that include functional language to comply with the Examiner’s request. If the Examiner disagrees or requires another submission, Applicants request that he contact the undersigned at the earliest opportunity to discuss any remaining objections to the figures.

### ***Objection pursuant to 35 U.S.C. §112 and 132***

The Examiner objects to the amendment filed on January 14, 2009 pursuant to 35 U.S.C. 132(a) because it allegedly introduces new matter into the disclosure of the invention. The Examiner also rejects claims 38-41, 43, 44, 47-50, and 70-73 pursuant to 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner argues that the originally filed disclosure is silent on “the range of about 1350 nm to about 2700 nm” and “fluence in a range of about 0.01 J/cm<sup>2</sup> to about 0.5 J/cm<sup>2</sup>.” Applicants respectfully disagree.

MPEP 2163.05 (III) provides:

With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of “25%-60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, *however a limitation to “between 35% and 60%” did meet the description requirement.* (Emphasis Added)

With regard to the wavelength range of “about 1350 nm to about 2700 nm,” the specification recites that “[t]ypical parameters for this treatment include wavelengths in the range of about 380 to about 2700 nm, preferably in a range of about 600-1400 nm, and more preferably in the range of about 800-1350 nm.” Para. [0058]. Thus, the originally filed specification is not silent on the range of 800-1350 nm. Rather, the wavelength of 1350 is the end point of the narrower range of about 800-1350 that falls within the range of about 380 to about 2700 nm. As such, the specification provides support for the range of “about 1350 nm to about 2700 nm.”

Claims 70 and 73 are hereby canceled, thereby obviating the basis of the Examiner’s objection to the recitation of a fluence range of “about 0.01 J/cm<sup>2</sup> to about 0.5 J/cm<sup>2</sup>” with respect to these claims. However, Applicants have amended claims 10, 60, 71 and 72 to recite a fluence in a range of “about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup>.” The specification discloses applying radiation to a treatment area “so as to expose the treatment area to a fluence in a range of about 0.1 J/cm<sup>2</sup> to about 1000 J/cm<sup>2</sup>, or more preferably a fluence in a range of about 5 to about 50 J/cm<sup>2</sup>.” Para. [0016]. As discussed above, the narrower claimed range falls within the range of about 0.1 J/cm<sup>2</sup> to about 1000 J/cm<sup>2</sup> and is supported by the specification. *See M.P.E.P 2163.05 (III).*

### ***Amendments to the Claims***

Applicants present the following claim amendments solely to expedite prosecution. These amendments should not be construed as Applicants’ acceptance of the Examiner’s rejection. Applicants reserve the right to prosecute any of the former claims in a continuing application.

In order to clarify their contribution to the art, Applicants have amended claim 10 to recite applying one or more electromagnetic radiation (EMR) pulses each having a pulse width in a range of about 1 microsecond to about 100 milliseconds, a wavelength in a range of about 360 nm to less than 600 nm, wherein the EMR applies a fluence in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup> to the treatment area.

Claim 38 is amended to recite applying at least one electromagnetic radiation pulse having one or more wavelength components in a range of about 1350 nm to about 2700 nm and a pulse width in a range of about 1 microsecond to about 100 milliseconds to a skin treatment area to deposit energy in one or more hair shafts in the treatment area so as to cause a change in elasticity of said hair shafts, the electromagnetic radiation applied to the one or more hair shafts being less than necessary to remove the respective hair shafts, so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area. Claim 71, which depends from claim 38, is amended to recite a fluence in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup>.

Claim 51 is amended to recite applying electromagnetic radiation having one or more wavelength components in a range of greater than 1200 to about 1400 nm and a pulse width in a range of about 1 microsecond to about 100 milliseconds to one or more hair follicles in a skin treatment area so as to modulate hair growth, and prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area, the radiation applied to the one or more hair follicles being less than necessary to remove the respective hair shafts. Claim 72, which depends from claim 51, is amended to recite a fluence in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup>.

Claim 60 is amended to recite irradiating a plurality of hair follicles in a treatment area with radiation of a wavelength, pulse width, and fluence suitable for decreasing curliness of at least a portion of said hairs, so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area, wherein the wavelength is selected to be in a range of about 380 nm to 600 nm, the pulse width is in a range of about 1 microsecond to about 100 milliseconds, and the fluence is in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup>.

Support for these amendments can be found throughout the specification, for example, at paragraphs [0014]-[0016] and in the claims as originally filed.

Further, Applicants have canceled claims 11, 18, 19, 21, 47, 67, 69, 70, and 73, and added new claims 74-79. Support for the new claims can be found throughout the specification, for example, at paragraph [0014]. No new matter is added.

***I. Rejections Under 35 U.S.C. § 102(b)***

**A. Rejections Based on Caisey**

The Office Action rejects claims 10-14, 16-21, 24-26, 32, 36-39 and 43 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,679,113 of Caisey et al. (“Caisey”).

**1. Claim 10**

Claim 10, as amended, discloses a hair treatment method that includes applying one or more EMR pulses each pulse having a pulse width in a range of about 1 microsecond to about 100 milliseconds and a wavelength in a range of about 360 nm to less than 600 nm to a skin treatment area to deposit energy in one or more hair tips in the area so as to cause heating of at least a portion of the hair tips so as to modify a shape of at least a portion of said hair tips, the EMR applied to the respective hairs being less than necessary to remove the respective hairs, so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area, wherein the EMR applies a fluence in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup> to the treatment area.

Caisey is directed to a process for bleaching hair using laser irradiation having a wavelength in the range of 300-1100 nm to degrade melanin within the hair. Caisey discloses a process for bleaching hair, but does not teach or even suggest the use of EMR to modify a shape of at least a portion of the hair tips to treat, reduce, or prevent PFB. Nor is there any reason to believe that the method of Caisey would necessarily result in the claimed method of modifying hair tips as Caisey fails to teach or suggest the combination of the wavelength, fluence and pulse width ranges recited in claim 10. In fact, Caisey teaches away from the pulse width range of “about 1 microsecond to about 100 milliseconds” recited in claim 10 by stressing that the “duration of the pulses may range,

for example, from 10 picoseconds to 100 nanoseconds” but “*must not be greater than approximately one microsecond.*” col. 5, lines 1-2; col. 2, lines 58-58 (emphasis added).

Moreover, Applicants teach that the wavelength range of “about 360 nm to less than 600 nm” provides distinct advantages for selectively depositing energy in hair tips to modify their shapes. In particular, Applicants teach that wavelengths in a range of 360-600 nm can limit the penetration of the light into the basal layer of skin while allowing for the absorption by melanin in the hair tips to selectively deposit of energy into the hair tips. Para. [0051]. In contrast, Caisey merely discloses a broad wavelength range of 300-1100 nm.

For at least these reasons, claim 10 distinguishes over Caisey. Claims 12-14, 16, 17, 20, 24-26, 32, 36, and 37 are allowable over Caisey at least because they depend, directly or indirectly, on claim 10.

## 2. Claim 38

Independent claim 38 recites a method of treating hair that includes applying at least one electromagnetic radiation pulse having one or more wavelength components in a range of about 1350 nm to about 2700 nm and a pulse width in a range of about 1 microsecond to about 100 milliseconds to a skin treatment area to deposit energy in one or more hair shafts in the treatment area so as to cause a change in elasticity of said hair shafts, the electromagnetic radiation applied to the one or more hair shafts being less than necessary to remove the respective hair shafts, so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area.

Caisey fails to teach or even suggest applying electromagnetic radiation having a wavelength component in a *range of about 1350 nm to about 2700 nm* to a treatment area so as to change the elasticity of a hair shaft so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area. Rather, as noted above, Caisey teaches utilizing radiation wavelengths in a range of 300-1100 nm for bleaching hair.

For at least these reasons, claim 38 distinguishes over Caisey. Claims 39 and 43 are allowable over Caisey at least because they depend, directly or indirectly, on claim 38.

## **B. Rejections Based on McDaniel**

The Office Action rejects claims 10-14, 16-21, 24-34, 36-41, 43, 44, 47-54, 56-64, and 67-73 pursuant to 35 U.S.C. § 102(e) as anticipated by U.S. Application Pub. No. 20030023283 of McDaniel (“McDaniel”).

### **1. Claim 10**

McDaniel is directed to “a method for stimulating hair growth in which the hair growth structure is exposed to a source of electromagnetic radiation having a dominant emissive wavelength from about 390 nm to about 1600 nm.” Para. [0012]. “Photostimulating the hair growth structure is then performed by maintaining the exposure of the hair growth structure to the source of electromagnetic radiation for a clinically effective duration and at a clinically effective light intensity.” *Id.*

McDaniel does not teach or even suggest the use of EMR to modify a shape of at least a portion of the hair tips to treat, reduce, or prevent PFB. Nor does McDaniel disclose applying one or more EMR pulses each pulse having a pulse width in a range of about 1 microsecond to about 100 milliseconds, and a wavelength in a range of about 360 nm to less than 600 nm to a skin treatment area, wherein the EMR applies a fluence in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup> to the treatment area.

McDaniel does not teach or suggest utilizing the wavelength range of “about 360 nm to less than 600 nm,” but rather discloses a broad wavelength range of 390 nm to 1600 nm. Further, to the extent that McDaniel discloses examples of the operating parameters for stimulating hair growth, *see* paragraphs [0148]-[0159], these examples clearly fail to meet each and every recitation of claim 10. In other words, in each of the examples at least one parameter (e.g., wavelength, pulse width or fluence) lies outside the ranges recited in claim 10.

For at least these reasons, claim 10 distinguishes over McDowell. Claims 12-14, 16, 17, 20, 24-34, 36, and 37 are allowable over McDowell at least because they depend, directly or indirectly, on claim 10.

## **2. Claim 38**

McDowell does not teach applying at least one electromagnetic radiation pulse having one or more wavelength components in a range of about 1350 nm to about 2700 nm and a pulse width in a range about 1 microsecond to about 100 milliseconds to a skin treatment area to deposit energy in one or more hair shafts in the treatment area so as to cause a change in elasticity of said hair shafts, so as to prevent, reduce, or treat PFB in the skin treatment area.

Although McDowell broadly discloses that wavelengths ranging from 390 to 1600 nm and pulse durations ranging from 0.5 microseconds to 10 minutes can be used in photostimulation or photothermal treatment, McDowell, however, fails to suggest the combination of parameters recited in claim 38 and the advantages the combination provides.

Further, to the extent McDowell discloses examples of the operating parameters for stimulating hair growth, one or more of the parameters lies outside the wavelength and pulse width ranges recited in claim 38.

For at least these reasons, claim 38 distinguishes over McDowell. Claims 39-41, 43, 44, 48-50, and 71 are allowable over McDowell at least because they depend, directly or indirectly, on claim 38.

## **3. Claim 51**

Claim 51 recites a method for controlling the growth of hair that includes applying one or more electromagnetic radiation pulses having wavelength components in a range of greater than 1200 to about 1400 nm and a pulse width in a range of about 1 microsecond to about 100 milliseconds to one or more hair follicles in a skin treatment area so as to modulate hair growth, and prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area, the radiation

applied to the one or more hair follicles being less than necessary to remove the respective hair shafts.

McDaniel does not teach applying an electromagnetic radiation pulse having wavelength components in a range of greater than 1200 nm to about 1400 nm and a pulse width in a range of about 1 microsecond to about 100 milliseconds to one or more hair follicles so as to modulate hair growth, and prevent, reduce, or treat pseudofolliculitis barbae (PFB). As discussed above, to the extent McDaniel discloses examples of the operating parameters for stimulating hair growth, these examples clearly fail to meet each and every recitation of claim 51.

For at least these reasons, claim 51 distinguishes over McDaniel. Claims 52-54, 56-59, and 72 are allowable over McDaniel at least because they depend, directly or indirectly, on claim 51.

#### 4. Claim 60

Claim 60 recites a method of treating hair by irradiating a plurality of hair follicles in a treatment area with radiation of a wavelength, pulse width, and fluence suitable for decreasing curliness of at least a portion of the hairs, so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) where the wavelength is in a range of about 380 nm to about 600 nm, the pulse width is in a range of about 1 microsecond to about 100 milliseconds, and the fluence is in a range of about 0.1 J/cm<sup>2</sup> to about 5 J/cm<sup>2</sup>.

McDaniel does not teach or even suggest the use of EMR to decrease the curliness of at least a portion of the hairs to prevent, reduce, or treat PFB. Nor does it teach or suggest the combination of wavelength, pulse width and fluence ranges recited in claim 60.

For at least these reasons, claim 60 distinguishes over McDaniel. Claims 61-64 and 68 are allowable over McDaniel at least because they depend, directly or indirectly, on claim 60.

## II. Rejections Under 35 U.S.C. 103(a)

The Examiner rejects claims 10-14, 16-21, 24-41, 43, 44, 47-54, 56-64, and 67-73 pursuant to 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,273,884 of Altshuler et

al. (“Altshuler”) in view of McDaniel. Initially, Applicants note that claims 12, 18, 19, 21, 47, 67, 69, 70, and 73 are canceled, thereby obviating the Examiner’s rejection with respect to these claims.

The Examiner alleges that “Altshuler teaches a device and method as claimed except for the particular pulse widths, fluences, and wavelengths a billionth of a nanometer different from the claimed ranges.” The Examiner thus relies on McDaniel for the teaching of the treatment parameters and argues that it would have been obvious to one ordinary skill in the art “to employ the pulse widths and fluences of McDaniel (‘283) in the device and method of Altshuler. . . , or alternatively, to employ the parameter interrelations taught by Altshuler et al in the device and method of McDaniel. . . .” Applicants respectfully disagree.

Altshuler discloses applying radiation wavelengths, e.g., in a range of 600-1200 nm, to heat the skin and/or at least part of hair follicles, e.g., the hair bulb. *See* col. 5, lines 61-62; col. 11, lines 35-36; col. 12, lines 26-28. And as discussed above, McDaniel fails to teach or even suggest the combination of parameters recited in independent claims 10, 38, 51, and 60.

For at least these reasons, independent claims 10, 38, 51, and 60 distinguish over the combination of McDaniel and Altshuler. Claims 12-14, 16, 17, 20, 24-37, 39-41, 43, 44, 48-50, 52-54, 56-59, 61-64, 68, 71, and 72 are allowable at least because they depend, directly or indirectly, on an allowable base claim.

### **III. New Claims**

Applicants have introduced new claims 74-79, of which claim 74 is independent. Claim 74 recites a hair treatment method that includes applying EMR in a range of about 360 nm to less than 600 nm to a skin treatment area to deposit energy in one or more hair tips in the area to raise the temperature of said hair tips to a range of about 50 to about 300 °C so as to modify a shape of at least a portion of said hair tips, the EMR applied to the respective hairs being less than necessary to remove the respective hairs, so as to prevent, reduce, or treat pseudofolliculitis barbae (PFB) in the skin treatment area.

The cited references alone or in combination fail to teach or suggest the recitations of claim 74. For example, there is no indication in Casey or McDaniel that the hair tips are heated to a temperature in a range of about 50 to about 300 °C. Similarly, there is no indication in the cited references to apply radiation to heat the hair tips to a temperature in a range of about 50 to about 300 °C so as to modify a shape of at least a portion of the hair tips so as to prevent, reduce, or treat PFB. Claim 74, therefore, distinguishes over the cited art and represents allowable subject matter. Claims 75-79 are allowable at least because they depend on an allowable base claim.

#### **IV. Conclusion**

In view of the above amendments and remarks, Applicants respectfully request reconsideration and allowance of the application.

In the event that the remarks are not deemed to overcome the grounds for rejection, Applicants kindly request a telephonic interview to discuss the remaining issues. In such case, the Examiner is kindly requested to telephone the undersigned representative at the earliest convenience

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 105090-230.

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Respectfully submitted,

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